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Deep Insert Earplugs

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PROJECT THESIS

Department of Mechanical and Industrial Engineering

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Preface

The project thesis was written at NTNU as part of the study program at Department of Mechanical and Industrial Engineering. It was carried out for SINTEF Digital during the autumn semester of 2017, as a continuation of an early phase project that the Acoustics department of SINTEF Digital had barely initiated. I got to know the people at SINTEF through the NTNU course Experts in Teamwork during the spring semester of 2017, and the problem was tailored to my field of Product Development and Materials Engineering. The cooperation with the company included idea generating and technical guidance at a frequent basis throughout the semester.

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Acknowledgment

First of all, I want to thank Odd K. Pettersen and Audun Solvang at SINTEF Digital for initiating the project and giving me the opportunity to take part in their development project on deep insert earplugs.

I'd like to express my sincere gratitude for the consultancy by my supervisors, Knut Aasland and Olav Kvaløy. Also, many thanks to co-supervisor Christer W. Elverum for guidance towards the end of the semester.

I appreciate all the support and assistance I have gotten throughout the semester. Without the goodwill from both the Department of Mechanical and Industrial Engineering at NTNU and SINTEF Digital, the project would not have been executable.

J.A.

Summary and Conclusions

The idea of a deep insert earplug is a relatively unexplored field in the world of non-custom hearing protective devices, and is exactly what has been looked into in this research. Through reviewing highly relevant anatomical theory, as well as different studies on ear canal geometry, the most prominent challenges of developing such an earplug have been pointed out. The literature survey has also included mapping out a fair range of existing corresponding variants on the market, to collect competitive benchmarking information. Based on this survey, an extensive work has been done on customer understanding and compiling of functional requirements. Four completely different concepts have been explored through morphological matrices, prototyping and physical testing. Even though several of the concepts have indicated some promising properties throughout the process, only one of them was extensively looked into. This exact plug, referred to as *Vacuum*, proved the concept of evacuating to decrease the cross-section, before ventilating and recover to original size at a preferred point in time. In other words, this plug can be shrunken down before insertion, and expand when properly placed. During testing, the evacuated plug yielded results that don't quite satisfy the required dimensions of a deep insert earplug. With some of the essential groundwork in place, further research and development need to be done in order to come up with a proper solution to the deep insert earplug.

Contents

Chapter 1

Introduction

1.1 Background

Earplugs are widely used as hearing protection, both for personal, military and industrial purposes. On today's market there are several products that are supposed to serve this consume, but all with certain setbacks. They tend to either be poorly dampening, causing occlusion, expensive, hard to insert or simply uncomfortable. In other words, the majority of these types of hearing protection is somewhat unpleasing to wear for longer periods of time, and chances of skipping the protection for reasons like this are high. The awareness of hearing health seem to be steadily increasing among people, and with good reason. To get an idea of the maximum justifiable noise exposure levels with corresponding durations that no worker exposure shall equal or exceed[1], see Table 1.1.

Problem Formulation

The ear and ear canal, much like any other part of our body, differs from person to person. These differences are also seen across genders and populations. Ultimately, this directly affects comfort and protection levels. It is therefore desirable, and a scope of this research, to investigate the possibility for

[1] National Institute for Occupational Safety and Health, *Occupational Noise Exposure – Revised Criteria 1998*, Cincinnati, Ohio: NIOSH, 1998, pp. 2

a uni-ear deep insert earplug with a high level of acoustic attenuation, comfort and ease of use.

The earplug will be applying to end users of traditional earplugs, like hearing protection in industry or noisy leisure activities.

Time per day	Sound Level (L_{Aeq}) [dB]	Ex. of corresponding source
24 hours	80	Busy roadway traffic
8 hours	85	Noisy restaurant
2 hours 30 min	90	Food blender
47 min	95	Inside of subway
15 min	100	Jack hammer
4 min	105	Snow blower
1 min 30 sec	110	Large aircraft (150m)
28 sec	115	Chainsaw
9 sec	120	Vuvuzela horn

Table 1.1: Sound pressure levels and max. justifiable durations.

Literature Overview

Some key themes have been obvious to deep-dive into in order to meet the requirements that has been stated in the problem formulation. First of all, an extensive look into the anatomy of the human ear have been crucial for understanding the physical challenges of inserting and fitting a deep insert earplug. Further, the definition of a deep insert earplug is clarified, and the pros and cons of such a concept are discussed. In order to understand the problems to be solved, it is important to get an overview of the existing variants of hearing protection on the market. There are lots of existing products, varying in shapes and materials, all with different benefits and set-backs.

These are all considered essential groundings for coming up with a comfortable and pleasing deep insert earplug. A detailed literature survey will be presented in Chapter 2.

1.2 Objectives

The main objectives of this project thesis are:

1. Diving into the anatomy of the human ear to enlighten the dimensional challenges of fitting a universal deep insert earplug.

2. Mapping out existing variants of earplugs, and detect problems and benefits with them.

3. Developing conceptual solutions, and explore them through morphological matrices and prototyping.

1.3 Approach

The objectives will be approached through two phases, in which the first two will be parallelly approached. The work of mapping out existing variants will be done by searching the market, consider shapes and solutions, and investigate how they are being used. Concurrently, as challenges and benefits with existing earplugs are discovered, the anatomy on the human ear will be looked into. This objective is considered one of the most important part of the research, especially with respect to the ear canal. Understanding the dimensional variances and behavings of the ear canal will be crucial in order to come up with a deep insert earplug concept that is comfortable and easy to use for the end user. After this research is done, a product development process can take place. This includes mapping out essential features, for instance by the use of morphological and requirements matrices, developing concepts and prototyping. Proper testing of the main concepts will then be next step. As for the dampening properties of the design, more sophisticated methods of measuring the sound level dampening effect has to be done in the Acoustics lab at SINTEF.

1.4 Structure of the Report

The rest of the report is structured as follows. Chapter 2 gives an introduction to the topics that have been reviewed in literature relevant to the thesis. This will present the groundwork done beforehand the product development phase, and make the cornerstones for the deep insert earplug. It will also enlighten the parts of the problem that remains to be done. Chapter 3 will shortly present product development methodology and the customer understanding that underlies the ideation and prototyping process in Chapter 4. Lastly, Chapter 5 sums up the project thesis through discussion and conclusion, before recommendations for further work are given.

1.5 Scope and Delimitations

The overall scope of this project thesis will, first and foremost, be developing and looking at possible ways to block the ear canal at a deep level. Exploring different concepts through rough functional prototypes will be emphasized, rather than necessarily true-size prototypes. The thesis will also be delimited by not paying too much attention to the acoustical dampening properties of the materials being used.

Chapter 2

Literature Review and Groundwork

This chapter is presenting some of the literature that is considered the most important. Themes that has to be taken into account in order to come up with a good solution to deep insert earplugs and avoid the major pitfalls, are here identified and cited. The sections will enlighten key aspects such as the external auxiliary canal (EAC), physiological theory on the ear, existing variants of hearing protection, and some relevant studies on earplug attenuation.

2.1 The Anatomy of the Human Ear Canal

The book *The Human Ear Canal* by Ballachanda (2013) has been one of the main sources in the process of getting to know the human ear canal, which is especially important in order to fit a deep insert earplug. This brings up a question that should be defined and explained:

> *What defines a deep insert earplug, and why is this preferable?*

Ballachanda (2013) defines a deep canal hearing aid as "... *a device that terminates beyond the second bend and makes contact with the bony portion of the external auditory canal*". See figure 2.1. This definition will also be applicable in the case of an earplug, as the term "deep canal" is only referring to how deep the tip of the product is fitting into the ear.

Figure 2.2 illustrates the anatomical basics of the human ear canal, which is part of the outer ear. The ear canal has a two-part skeletal structure. It has a lateral part, the *cartilaginous* canal, consisting of elastic cartilage, and a medial part, the *osseous* canal, consisting of bone. For

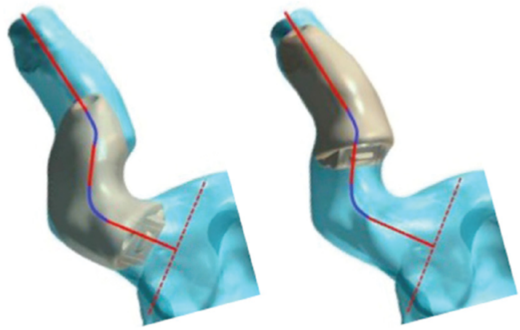


Figure 2.1: Two completely-in-the-canal (CIC) products, where the deep fitting CIC is shown to the right. Illustration by Starkey Laboratories, Ch. 7 Deep Canal Hearing Aids, The Human Ear Canal, Ballachanda, 2013.

The ear canal is not straight, but has a rather complicated geometrical appearance as it moves from the entrance (concha) and in towards the tympanic membrane (TM), also known as the eardrum. As can be seen in Figure 2.2 it has two bends, creating a twisted cavity with dimensional alterations along the length. At the fist bend the canal bends upwards, before it turns downwards at the second bend, near the eardrum. To get a maximum attenuation effect from a hearing protection device (HPD) like an earplug, it is desirable to plug the ear canal at the bony part, so that it is only bone conduction transmission paths that are restrictive in terms of attenuation. As a reference to the level of attenuation, Berger et al. (2003) showed through real-ear attenuation at threshold (REAT) measurements that deeply inserted foam plugs are able to yield maximum attenuation levels at 500Hz frequencies of 47.8 dB. Another possible benefit with deep insertion is that the bony part of the EAC will probably be less in play than in the cartilaginous in the case of movements (e.g. moving the jaw). The catch with plugging the bony part is the thin and easily irritable skin of the osseous canal. Ballachanda (2013) state that the thickness of the osseous canal skin measures approximately 0.1-0.2 mm in thickness, down to as little as one fifth of the cartilaginous canal skin thickness. A journal article by Staab et al. (2000) points out that even a pressure of 0.5 g/mm^2 in the bony canal, equal to the weight of a piece paper, is reported to cause pain. This proves the kind sensitivity that deep insert HPDs are dealing with.

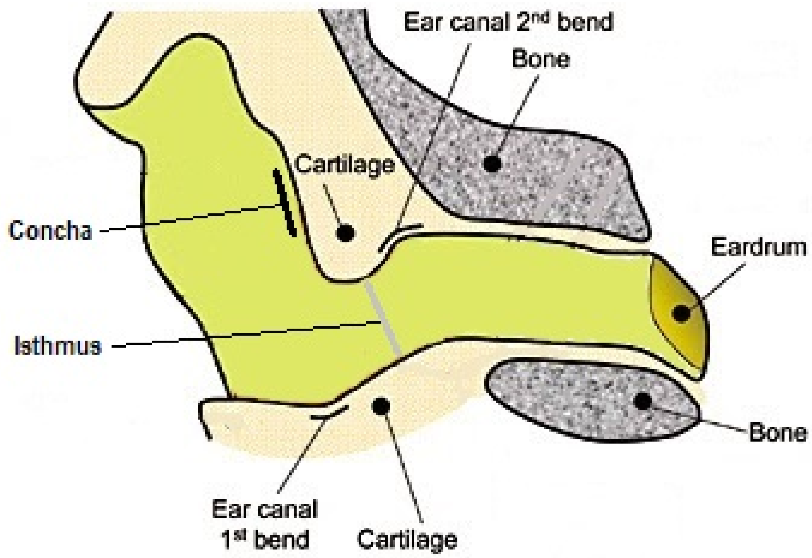


Figure 2.2: Simple anatomical illustration of the human ear canal.

2.2 Ear Canal Dimensions

A key factor for developing a deep insert HPD is looking at the physical dimensions of the ear canal. This is fundamental in determining size and shape of the of the device, both radially and axially of the ear canal. It has to be small enough to get in to the osseous canal, but with no danger of going too close to the tympanic membrane. The narrowest portion of the canal, *isthmus*, is stated by Ballachanda (2013) to be located right in the junction between the cartilagionous and osseous canal, which will have to be passed in order to accomplish a deep insert earplug. Several methods have been developed throughout the years on dimensional analyzing of the ear canal, and some of the results are presented in table 2.1.

Parameters	**Total** (n=280) [mm]	**Male** (n=160) [mm]	**Female** (n=120) [mm]
Length	23.5 ± 2.5	25.2 ± 2.6	22.5 ± 2.3
Longest diameter	9.3 ± 0.9	9.7 ± 1.1	8.5 ± 0.7
Shortest diameter	4.8 ± 0.5	5.1 ± 0.7	4.4 ± 0.3

Table 2.1: External ear canal measurements, gathered from 280 silicone impression molds of 140 cadavers. Adapted from Staab et al. (2000).

These measurements are done on cadavers, not from live individuals, and thus there may be some minor aberrations from reality. The measuring endpoints are also not directly specified. However, these measurements seem to a more practical approach for this exact purpose than e.g. the measurements done by Stinson and Lawton (1989), illustrated in Figure 2.3. Stinson and Lawton (1989) also gathered cross-sectional areas from studying 14 individual ear canals. The results from these measurements have been charted in Figure 2.4, as a function of position along the curved S-axis. Even though the cross-section has more of a random oval-like shape, these measurements can be used as a guideline for how a uni-earplug should be designed. For the sake of simplicity, if assuming a circular shape along the S-axis and using the same measurements for the cross-sectional area, the diameter of the cross-section is given by $d = 2 * \sqrt{A/\pi}$, and shown in Table 2.2.

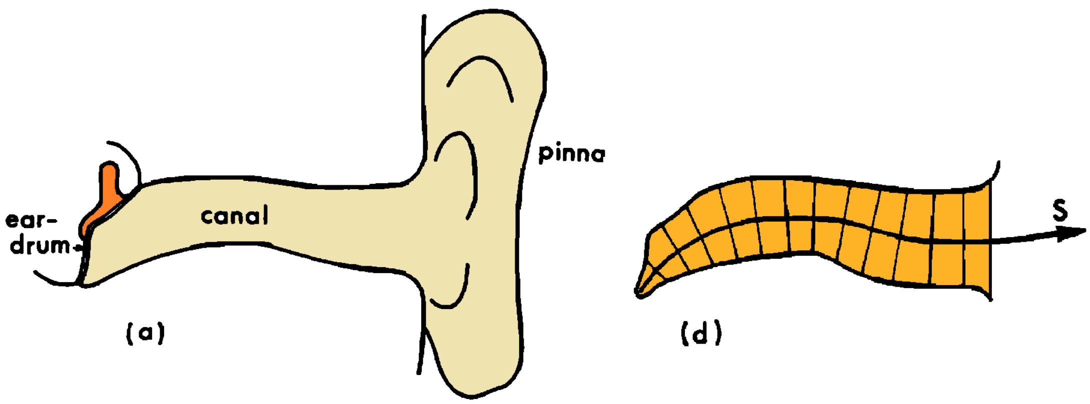


Figure 2.3: Illustrations from Stinson and Lawton (1989) and how their measurements was done from the very inner point of the tympanic membrane, following center line S. The average results for males and females were 31.8 mm and 29.2 mm, respectively.

Diameter	Position, S [mm]						
	0	5	10	15	20	25	30
Mean [mm]	0	5.6	7.0	8.0	7.8	8.6	9.8
Min. [mm]	0	4.5	5.3	6.0	5.9	6.7	8.0
Max. [mm]	0	6.4	8.3	9.2	9.1	10.5	11.0

Table 2.2: Mean, min. and max. diameter along the S-curve, based on area data from Stinson and Lawton (1989).

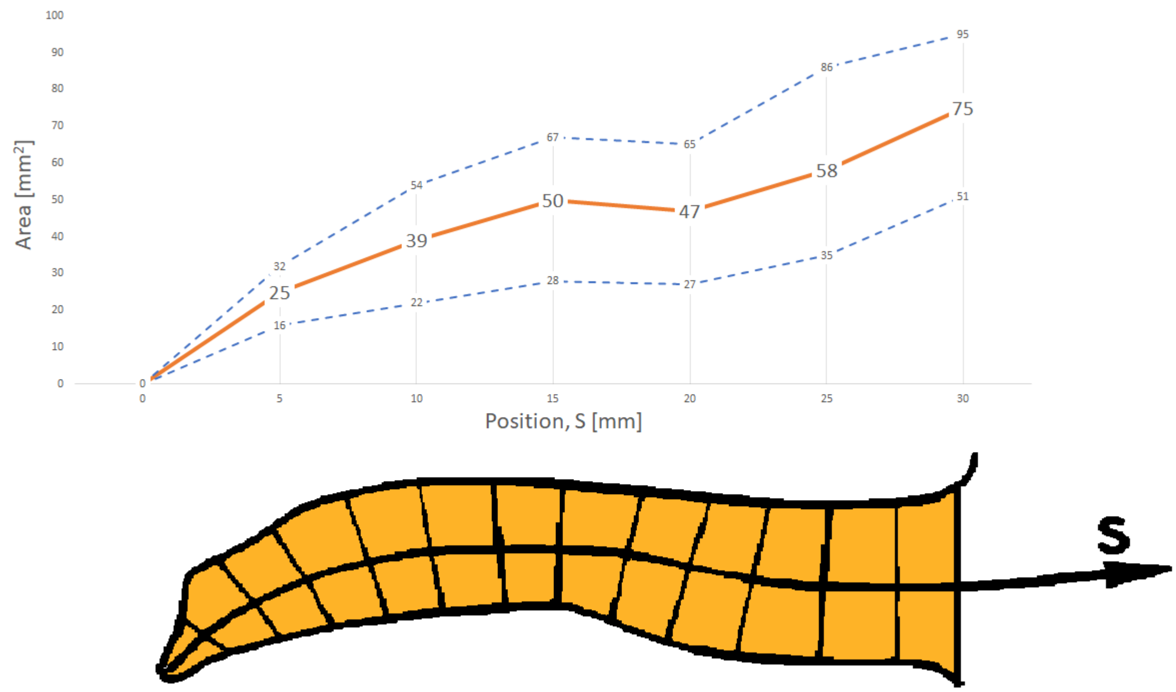


Figure 2.4: Measurements gathered from Stinson and Lawton (1989), showing the average cross-sectional area from a study of 14 individual ear canals. The dashed curves show the range of variation.

2.3 Hearing Protection

2.3.1 Existing Variants

There are lots of existing variants of hearing protection on today's market, ranging from a couple of dollars to several hundreds of dollars a pair. The fact that this development project is aiming at a non-custom, uni-ear HPD is narrowing down the range. Also, most of the conventional earplugs on the market are not categorized as deep fitting, even though some of them can reach these depths if inserted correctly. Nevertheless, the world of hearing aids is highly actual in this research. Most of these variants are specifically designed to perform comfortably with deep insertion for longer periods of time, and thus some of these are also represented. The main examples are listed in Table 2.3, comparing the various features and specifications. For the sake of this thesis, only stand-alone earplug HPDs are of interest, which leaves out earmuffs and head-covering protection like helmets.

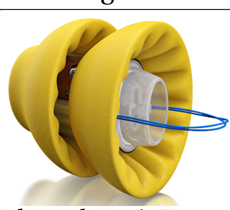
Model	**Type**	**Function**	**Material**	**SNR**	**Spacial features**
 3M E-A-R Classic™	Roll-down	HP	PVC	28dB	•Economical
 3M E-A-R Push-Ins™	Push-to-fit	HP	PU	38dB	•No roll-down •Hygiene fitting
 Honeywell SmartFit®	3-flange	HP	CMT	30dB	•One-size •Adapt to EAC shape
 Honeywell Clarity®	4-flange	HP	Molded	22dB	•Uniform attenuation •All-day comfort
 The Songbird	Mushroom	HA	Molded	N/A	•Uni-ear design •Deep-fitting •Disposable
 Phonak Lyric™	2-flange	HA	Foam	N/A	•100% Invisible •Deep in the ear canal

Table 2.3: Variants matrix for earplugs.
HP = Hearing protection
HA = Hearing aid

2.3.2 Bone Conduction

When the earplugs are properly inserted and penetrating deeply into the ear canal, what limits the attenuation is bone-conduction (BC). Berger et al. (2003) provide indication that BC limits the achievable attenuation to a mean value range of 40 to 60 dB, depending on the frequencies. REAT values from measuring the limiting attenuation levels of conventional foam earplugs are further reviewed in subsection 2.3.3.

2.3.3 Foam Earplug Attenuation

How great the obtainable attenuation with a foam earplug is, is dependent on several factors. Choice of material i obviously affecting this, but one of the most determining factors will be insertion of the plug. A deeply inserted (DI) foam plug is by Berger et al. (2003) stated to reach about 80% to 100% of the ear canal depth. *E-A-R® Classic® Plus* high-attenuation foam plugs, with a length of 24 mm, was in this study used to get REAT values and obtain the BC limits of humans. It was done by measuring the maximum attenuating effect of these plugs when deeply inserted. The results are shown in Table 2.4 across the frequency range.

Value	Frequency [Hz]						
	125	250	500	1000	2000	4000	8000
Mean [dB]	39.9	44.4	47.8	43.7	37.4	44.4	47.0
SD [dB]	5.5	4.8	3.5	4.2	2.9	3.7	4.7

Table 2.4: Mean REAT and standard deviation values from Berger et al. (2003).

What Remains to be Done?

With some of the most essential literature review and groundwork in place, the actual developing task can be taken on. Before being able to embrace the design phase, a proper work on customer understanding has to be done. Then an ideation and prototyping phase can take place.

Chapter 3

Product Development Methodology

3.1 Customer Understanding

The deep insert earplug is aiming at end customers using traditional earplugs, in light industry or sleeping for instance. Looking at the industry example, an important thing to consider is the part of the earplug that can be conflicted by other safety equipment. The blocking part ("tip") of this earplug will also be relevant for users of hearables, which spans several usages in the market.

This HPD is supposed to give the end customer added value through a design that meet the following three requirements:

- Usability
- Comfortability
- Noise reduction

Inserting an earplug is not necessarily a straight forward process, and it requires right sized earplugs and right technique. By not inserting the plug properly, chances of getting inadequate protection are high. It is therefore desirable to have an alternative earplug that is easier to insert deeply than existing variants. Easily insertable deep insert options are obtainable with custom moulded impressions, but then again the usability is heavily decreased regarding the moulding process. The price will also be a considerable set-back with customized options.

The skin in the ear canal is thin and easily irritated. Irritated skin is often the case for long time use, where pressure and minor movements of the earplug causes discomfort or pain. Insertion of the earplug causes friction that also contributes to lack of comfort. This is especially problematic with an already irritated ear canal, which can bee seen after long time use or several insertions of the plug. Discomfort is not just a problem in itself, but can lead to reluctant users that avoid using the hearing protection.

The attenuating part of the product is expected to achieve attenuation of the same magnitude as with an active system, but with considerably lower average sales prices (ASPs). At the same time, there is no need for battery changes or recharging, and the physical size of the device is smaller. Physical size is a parameter that that affects comfort of the plug in applications of sleeping for instance. By reducing the external part of the plug, the plug will be much more comfortable for sleeping purposes or with additional safety equipment such as helmets and glasses.

The concepts of the deep insert HPDs are also supposed to yield properties that reduces risk of blocking the ear canal with cerumen, which can be a problem with conventional earplugs.

3.2 Product Development Methodology

With a solid customer understanding and well defined needs established, the groundings are set for the phases of concept development and product designing. This section will take a closer look at the methodologies and prototyping methods relevant to this research.

3.2.1 Customer Needs and Product Specification

Before being able to make key decisions about the product, necessary knowledge have to be generated from core application requirements. This contributes in breaking the circular dependency of an iterating, agile approach, and is especially effective for eliminating rework.

After having identified the product opportunities and established a good understanding of customer needs, the next step is to define product specifications. A set of specifications are then established in order to have clear guidelines for designing and engineering the product. This includes defining measurable details about what the product has to do to meet customer requirements, separating from eventual competitors and making sure that it is technically realizable. This is further described in Ulrich and Eppinger (2012) as a set of steps, as listed below.

1. Prepare a list of metrics.
2. Collect competitive benchmarking information.
3. Set *ideal* and *marginally acceptable* target values.
4. Reflect on the results and the process.

This sets the primer for identifying the constraints in the early Set-Based Design process, which will be further investigated in the next subsection.

3.2.2 Set-Based Design

A hearing protection product specifically classified as a deep fitting, uni-ear and non-custom earplug seems to never have been developed. This makes this a new product development (NPD) process and is the key factor for choice of development method. Few to none variants have earlier been developed, making it unfavourable to eliminate any possible solutions in the early phase. This is exactly where Set-Based Design (SBD) is an appropriate way of attacking the development process, which was first seen in Toyota's development line and documented by Ward et al. (1995).

SBD is, in short terms, a way of increasing flexibility while reducing the amount of rework throughout a development process. There are several ways to accomplish this, but one of the most important is *deferring decisions* as long as possible. By focusing on constraints, based on the findings in product specification, it is possible to keep multiple optional solutions open and tarry decision making until necessary. This means keeping them as long as the options are economically and technically feasible.

The nature of a NPD, with high uncertainties, makes SBD hugely favorable. Not just because of the high flexibility that keeps room of solutions open for the knowledge to be gained, but also the fact that it reduces or even eliminates the cost of change at later stages. This can often be due to little or no need for rework, which is the case of learning something critical late in the development process that invalidates prior assumptions. Because SBD have managed the development in a way that these assumptions are delayed, reliable decisions don't need to be done until the required knowledge has been gained. A great way to accomplish this is by the use of front-loading, with reducing uncertainty and gaining essential knowledge through early prototyping.

According to Ghosh and Seering (2014) the fundamentals of SBD is keeping as many feasible options open as long as possible, but to a reasonable extent. In other words, no alternatives shall be eliminated as long as there is no logical reason for it. In contrast to a Point-Based Design (PBD) approach, which is graphically contrasted against SBD in Figure 3.1, this means that the space of solutions will narrow down through exploring several options parallelly. In developing a new product, where the range of competetive options is next to closed, it makes great sense to keep all possibilities open as long as nothing militates against it.

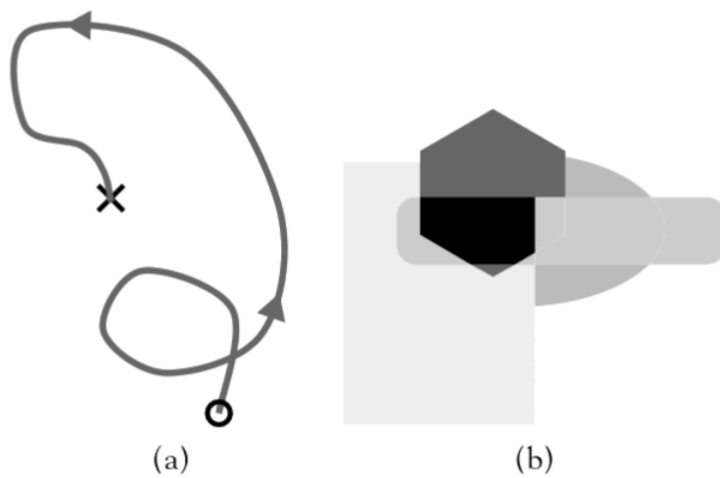


Figure 3.1: Illustration comparing PBD with SBD. PBD progressively refines one single concept towards a defined goal, or at least to a point where the developers are satisfied, while SBD is a set of solution spaces constrained by the knowledge that is being gained. Illustration gathered from Smith (2007).

As illustrated in Fig. 3.2 a Set-Based approach differs quite a bit from a Parallel Development, where the Set-Based phase can be seen as constrained spaces with lots of possible solutions to the subproblems. These spaces are narrowing down as new discoveries are accomplished and makes a progression to a few parallelly developing distinct options.

The approach of implementing SBD in NPD is done by dividing the problem into subsystems and rapidly prototype concepts and solutions from an early stage. To get an easy overview of the concept of Set-Based Product Development (SBPD) Ghosh and Seering (2014) has listed seven

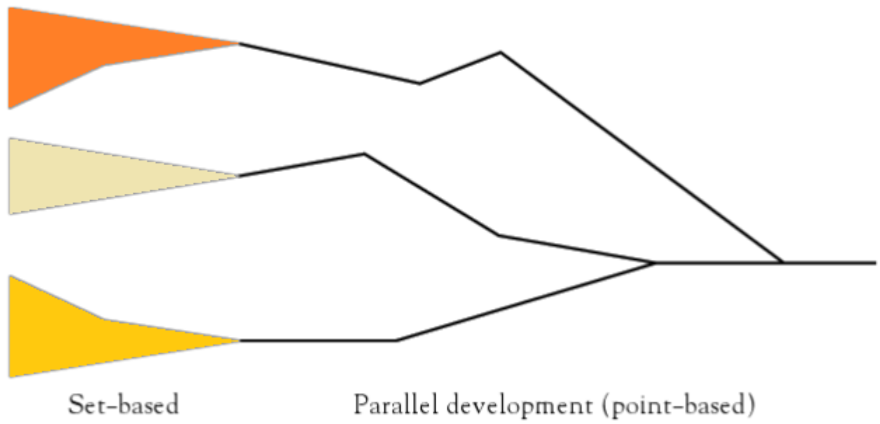


Figure 3.2: The time line of a process, progressing from a Set-Based Development to a Parallel Development. Illustration from Smith (2007)

main characteristics:

- Emphasis on frequent, lo-fidelity prototyping.
- Tolerance for under defined system specifications.
- More efficient communication among subsystems.
- Emphasis on documenting lessons learned and new knowledge.
- Support for decentralized leadership structure and distributed, non-collocated teams.
- Supplier/subsystem exploration of optimality.
- Support for flow-up knowledge creation.

One important factor in order to make this SBD work out is making sure that one does not get too attached to certain solutions. This will draw focus away from other possible options and cause a "tunneled" way to a finished product. One of the world's leading design firms, IDEO, has a philosophy that implies following what they call "the three R's": rough, rapid and right. By doing this in the prototyping process, one avoid using too much time on a high fidelity solution that possibly won't work, while still ensuring a solution conveying the concept and continuously reducing uncertainties.

3.2.3 Set-Based way of Prototyping

The importance of a proper way of prototyping, in order to succeed with a SBD process, is now enlightened. Functional prototypes are important tools in NPD because they make the most effective way of gaining knowledge of a concept and mitigating risks and uncertainties. At some point it is crucial to start answering feasibility questions, and this is where the pompous results from Design Thinking will somehow come in short.

In contrast to a Point-Based functional prototype, where you force your way through different takes on one single idea, a Set-Based (SB) approach will imply doing several individual tests to learn and establish relationships between them. Where the Point-Based prototyping may give limited learning potential, with an "either-or" result, the SB way of prototyping typically breaks it down to sub problems that are concurrently engineered, each iterating at its own. This is what Toche et al. (2012) refers to as *multiplying prototypes*, where the design practitioners are extensively exploring different opportunities. This will eventually lead to a convergence towards superior, or at least optimal designs.

Despite being a seemingly easy choice for bouncing into as many unknown ideas as possible in NPD, SB prototyping sure has its limitations. First of all it requires a fair amount of resources in order to build and test a lot of prototypes. Secondly, the concepts may be hard do decompose, and with subsystems so dependent that they cannot be developed separately.

3.3 Functional Requirements

3.3.1 The Kano model

It is useful to have some proper guidelines when classifying and organizing a products functional requirements. To easily cope with this, the *Kano model* has been used, described by Emery (2006) and illustrated in Figure 3.3. This model addresses three types of requirements in order to satisfy the customer:

- Basic needs

- Performance needs

- Delighters

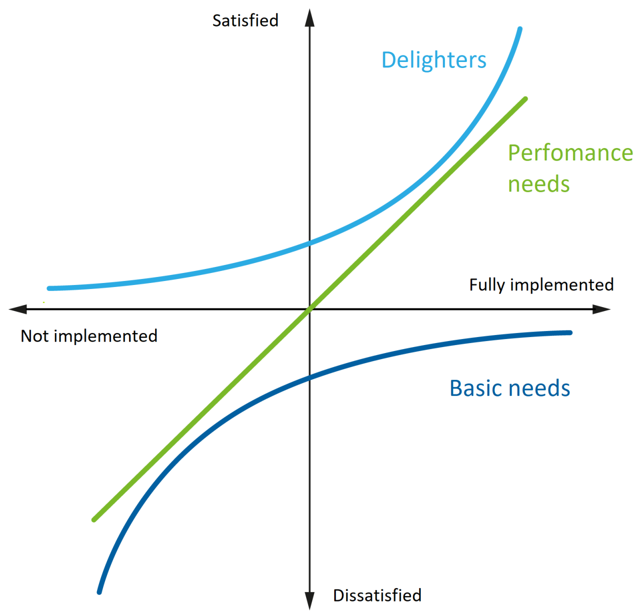


Figure 3.3: The Kano model (Kano 1984)

Basic needs refer to the bare minimum of what is expected of the product. A product not satisfying these requirements will lead to dissatisfied customers. Performance needs are the types of characteristics that increases or decreases customer satisfaction by their degree. Delighters are attributes that not necessarily are expected of the product, but however will lead to increased customer satisfaction.

3.3.2 Functional requirements matrix

All aspects of production and prices have been neglected at this stage, where concepts and functions are of highest priority. Even some of the features mentioned in Table 3.1 will be of lower priority in this project thesis.

Feature	**Basic need**	**Performance need**	**Delighter**
Attenuation*	x		
Sizes for every wearer	x		
Skin-friendly	x		
Easy insertion		x	
Easy removal		x	
Low pressure to the EAC		x	
Comfortable long-term wear		x	
Soil-resistant		x	
Reusable			x
Available as corded pairs			x
Visibility for compliance check			x
Uniform attenuation across frequencies			x

Table 3.1: Functional requirements matrix in accordance to the characteristics of the Kano model. *Single Number Rating (SNR) according to the International Standard ISO 4869 (Acoustics – Hearing Protectors). The recommended SNR is based on the noise environment that the hearing protection aims at.

Chapter 4

Design and Development

4.1 Ideation and Prototyping

The main goal of this project thesis is developing and exploring conceptual solutions to a deep insert earplug, and particularly with attention to the mechanism of expanding the earplug. From early on, the option of being able to control when the plug would expand, was highly focused on. This is due to the nature of the ear canal, with the narrowest part, *isthmus*, being on the outer side of the osseous canal, where the plug is supposed to reach.

4.1.1 Concept Matrix

The most prevailing concepts on the deep insert earplugs are presented in Table 4.1.

4.1.2 Concept 1: *Inflatable bladder*

Concept no. 1, the *Inflatable bladder*, is a spin-off of an idea that was developed by SINTEF Digital, illustrated in Fig. 4.1. The concept is based on the principle of injecting fluids into a bladder, through a flexible pipe. This could for instance have been done by using the click system from a retractable pen, which is a continuation of the original concept that utilizes a kind of syringe for the injection. The concept of an inflatable bladder was never really explored too deeply, as some major challenges was pointed out from the very start. Despite the fact that it could have achieved even pressures at the osseous canal, as well as easy insertion, the concept have some

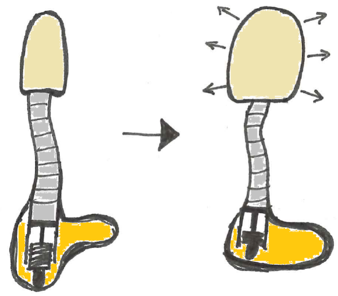
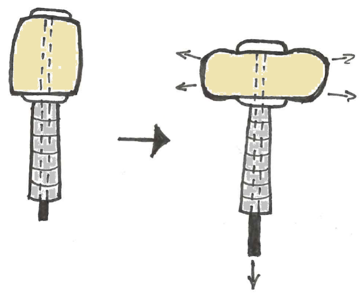
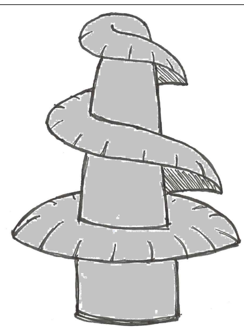
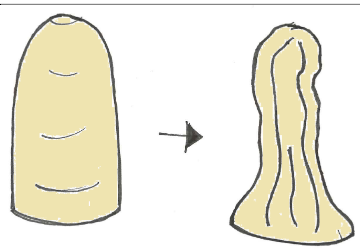
Concept	**Expanding**	**Attenuating material**	**Pros**	**Cons**
 1. *Inflatable bladder**	Fluid injection	Fluid	•Even pressure •Good noise reduction •Tiny when deflated	•Frangible
 2. *Squeeze*	Mechanical squeezing	Foam	•Good noise reduction •Controllable cross section	•Mechanically challenging •Risky if stuck
 3. *Screw*	N/A	Silicone	•Takes care of the ear wax •Reusable •Good noise reduction •Uni-size	•Requires screwing •Not necessarily obtaining "deep insert"
 4. *Vacuum*	Air inflation	Sealed foam	•Tiny when evacuated •Reusable •Good noise reduction	•Requires several sizes •Keeping the vacuum can get very delicate

Table 4.1: Concept matrix for the proposed ways of "plugging" the EAC.

issues. One of the issues is that it is considered frangible with the thin bladder and flexible pipe to be put in and out of the EAC. The sound attenuating effect of such a concept is considered to be good. As stated in Godin (2016) the sound transmission from air to water is poor because of the highly contrasting acoustical impedance of the two mediums. The attenuating effect of the *Inflatable bladder* is assumed to be even greater in the case of our HPD, as we are dealing with one more contrast interface, with an air-water-air transmission. Some of the other concepts were pulling a bit harder, so despite the promising aspects of this idea, lack of time left this concept rather unexplored.

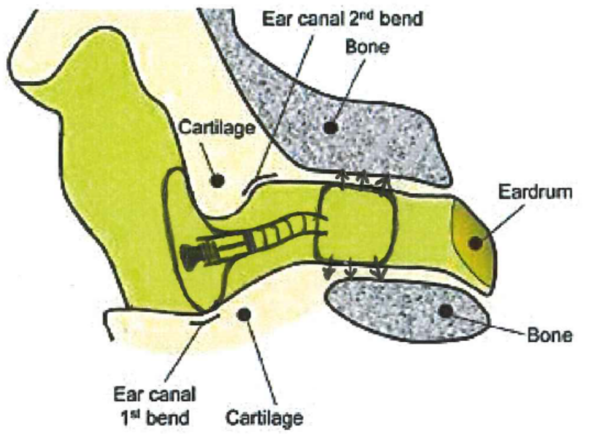


Figure 4.1: *Inflatable bladder* inserted in the EAC. Expansion concept provided by SINTEF Digital, Trondheim.

4.1.3 Concept 2: *Squeeze*

The second concept, *Squeeze*, was an idea that came up as some of the earliest. It has the advantage of having a highly controllable cross section, so that *isthmus* can easily be passed before expanding. At the same time the polyurethane (PU) foam, as a successfully proven concept through almost any standard foam earplug, has great sound attenuating properties. It expands when mechanically squeezed until sealing against the ear canal.

Prototyping

This was briefly tested out through a few iterations, but was found to be mechanically challenging to get around, and with less of a cross-sectional expanding than expected. See Figure 4.3 for one of the prototypes investigating this exact mechanism, showing the diameter increasing less than 1 mm from sqeezing. This prototype was only done with the foam from Würt X-100 earplugs, and other chemical variants of foam will possibly behave differently. The potential for

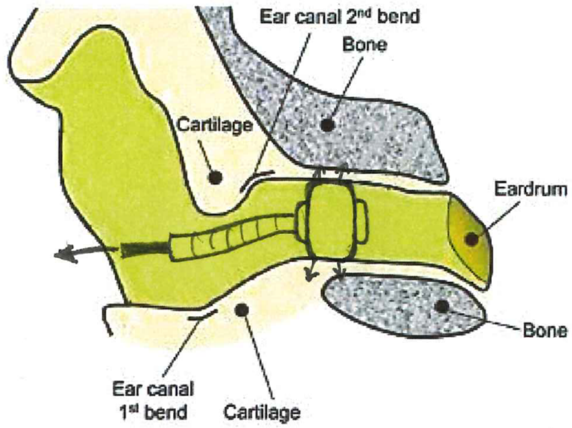
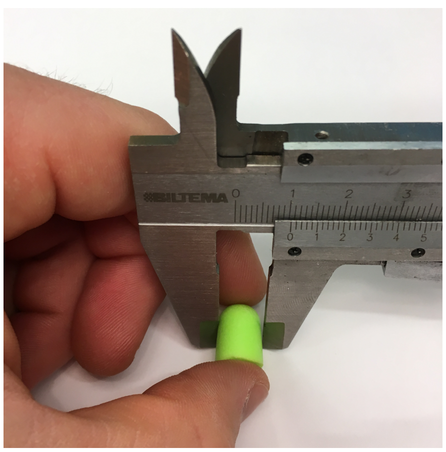
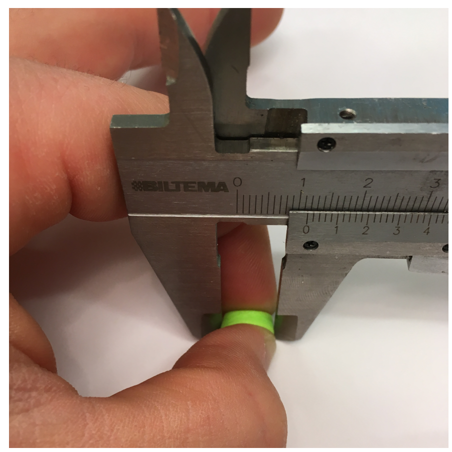


Figure 4.2: *Squeeze* inserted in the EAC.

a breakage or failing contraction of the cross section, leaves this concept a bit on the risky side, and no further exploration was conducted.



(a) PU foam plug unsqueezed, length=15mm.



(b) PU foam plug squeezed, length=6mm.

Figure 4.3: A small PU foam plug squeezed by hand to test how it reacts to axial compression, regarding cross-sectional expanding. The result was a diametrical increase of less than 1 mm, from Ø1.02 to Ø1.11.

4.1.4 Concept 3: *Screw*

The concept of the *Screw* plug was inspired by an ear wax removing tool that cleans up the ear canal by the use of a rotating elastic screw, illustrated in Figure 4.5a. The idea was a product of one of the challenging aspects of deep insertion, namely that ear wax is likely to be pushed in towards the eardrum. By using a helically shaped flange on a flexible core, the ear wax could be transported out of the ear canal while screwing the plug in.

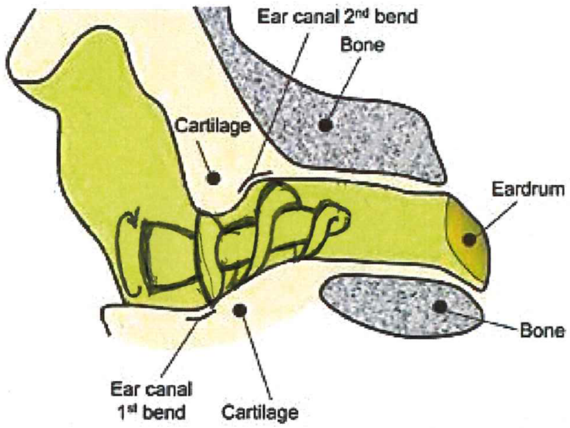
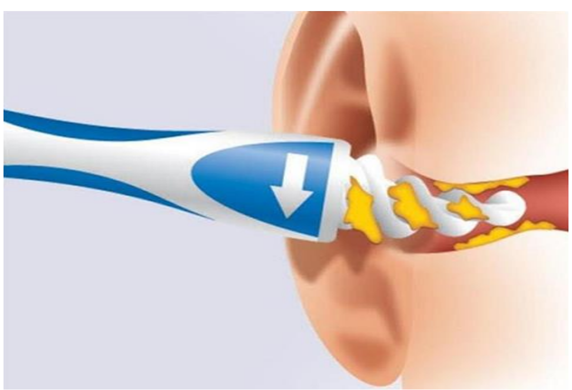
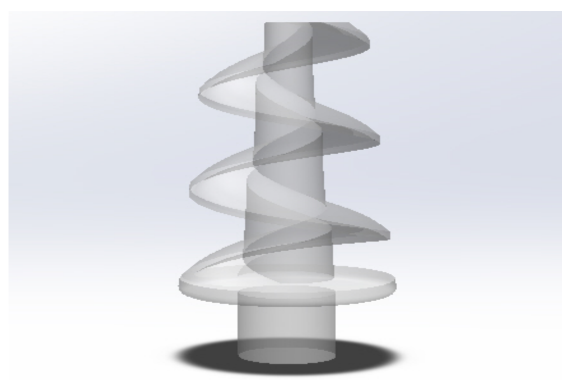


Figure 4.4: *Screw* inserted in the EAC.



(a) Ear wax removal tool.

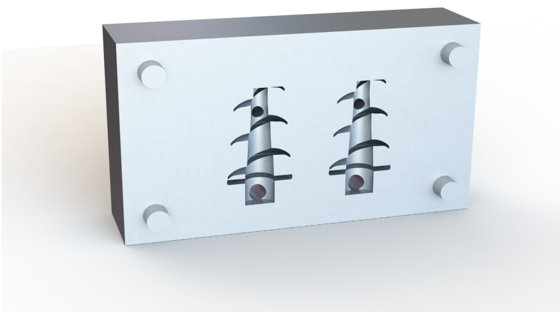


(b) The *Screw* concept.

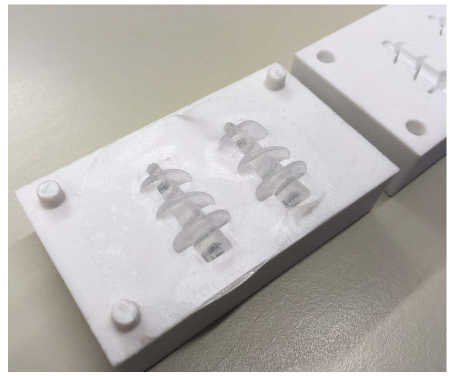
Figure 4.5: Ear wax removal tool (a) as an inspiration for the *Screw* plug (b).

Prototyping

A basic mould was designed in the CAD tool Solidworks. As shown in Figure 4.6a, a two-piece mould was designed with two cavities of the screw shaped earplug, as well as one sprue and one riser for each cavity. The mould was then 3D-printed with a PLA filament.



(a) Top mould piece from CAD.



(b) Cured silicone mould.

Figure 4.6: From CAD design (a) to moulded silicone plug (b).

The manufacturing of the *Screw* moulds was done by clamping the two-piece mould together and injecting addition vulcanizing silicone material[1] until the the risers were filled up. The mould cured for 20 minutes before it was taken apart. Finished product are pictured in Figure 4.7.

Figure 4.7: Finished moulds of the *Screw* earplug.

No more iterations were done on this concept. Although this earplug would help solving the

[1] Dreve Biopor® AB 25 Shore

ear wax problem, being reusable and unisize, the idea was not taken any further. It is proven possible and might work, but stands out in the concept range as less of a "deep insert" solution.

4.1.5 Concept 4: *Vacuum*

The *Vacuum* concept was an idea that was continously evolving throughout the developing process. It is based on the principle of deflating, or evacuating, a plug, so that it can be inserted deeply into the ear canal without major conflicts. When properly placed in the osseous canal, air can be ventilated into the plug so that it expands against the canal wall, as illustrated in 4.8.

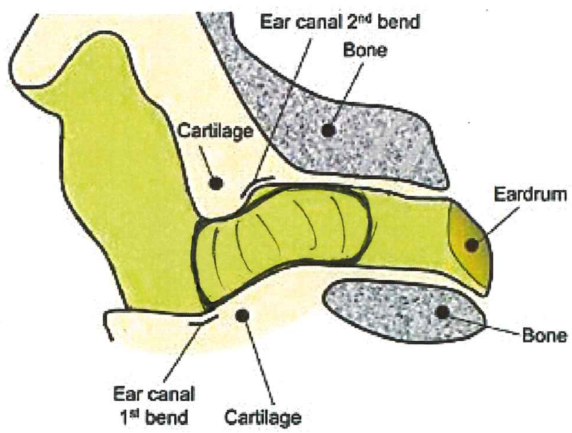


Figure 4.8: *Vacuum* inserted in the EAC.

Prototyping

A number of iterations and prototypes was done to explore this concept. First, a bunch of plugs[2] were prepared for prototyping. First of all, the surfaces had to be sealed in order to get evacuation working. The plugs were cleaned and glued onto plastic pipes, with the pipes being the ventilation system carrying air in and out, as shown in Figure 4.9.

[2]Würth X-100 earplugs.

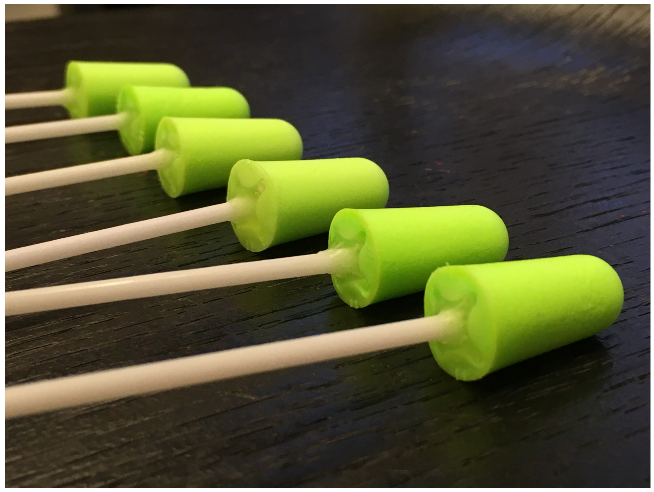


Figure 4.9: The test pieces. PU plugs glued onto plastic pipes with *Tangit PVC-U* adhesive.

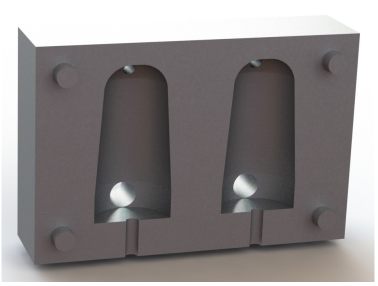
The next step was to properly coat the plugs so that they were completely air tight. The challenge here was to find a way to coat it without being at the expense of geometry, flexibility and comfort. Some of the early iterations are shown in Figure. 4.10. None of the sealings in Figure

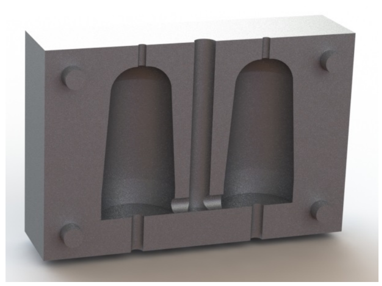
(a) Burnt surface. (b) Condom. (c) Rubber spray. (d) Sanitary silicone.

Figure 4.10: Four early stage takes on sealing the foam plugs.

4.10 worked significantly well in terms of being air tight, although one the test pieces coated with sanitary silicone sealant showed promising results. The tests were conducted simply by squeezing the plugs flat, and then blocking the pipe opening to see if it inflated or not. Even though the latter variant held tight, the final shape came out way too bulky and inconsistent. The next step was trying to make a silicone mold, using the same test pieces as cores. This way it was possible to get more consistent geometries.

Once again the moulds were modelled in Solidworks and 3D-printed with PLA filament. The


(a) Top mould piece from CAD, v1.


(b) Mould piece from CAD, v2.

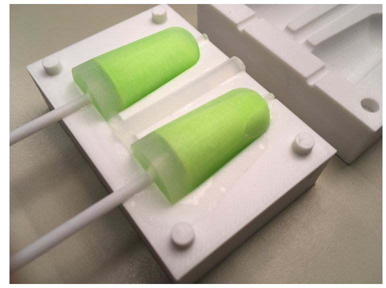

(c) Cured plugs from mould v2.

Figure 4.11: From CAD designs (a) and (b), to moulded silicone plug (c).

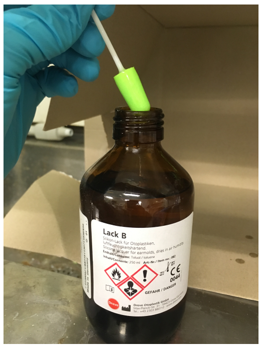
first version (Figure 4.11a) was a bit problematic in terms of always producing plugs with an area uncovered with silicone. The mould design was improved (Figure 4.11b) by ensuring that the foam cores were moulded in a straight up position, and with one sprue filling both cavities. The result can be seen in Figure 4.11c. The test pieces (cores) were precisely placed and centered before the mould were clamped together, but the same "dry spot" seemed to appear on every product. The moulds were 1 mm oversized all over the surface of the foam plugs, so minor misalignments can be the reason for these uncovered areas, which is closely shown in Figure 4.12a. Leaving the "dry spots" out of account, these plugs are perfect for testing the evacuation concepts only if sealed. This was done in Figure 4.12b by adding a thin layer of the same addition vulcanizing silicone material. This prototype showed outstanding results in terms of an air tight solution, and proved only to let air in and out of the plastic pipe.


(a) Moulded *Vacuum* plug with "dry spot".


(b) Moulded plug sealed with silicone.

Figure 4.12: From moulded plug with an area uncovered of silicone (a) to a completely sealed plug (b).

To further improve the concept of the vacuum plug, a silicone lacquer[3] was used. This is a liquid that is traditionally used for dipping moulded earmolds. The dipping was done with the same test pieces used in earlier prototypes of the *Vacuum* plug, as shown in Figure 4.13.



(a) The dipping process.

(b) Test pieces curing.

(c) Cured silicone layer.

Figure 4.13: Dipping the test pieces in silicone lacquer (a) and letting them cure for 20 min (b). Finished plug (c).

Ideally the layer of silicone lacquer should be as thin as possible. This is preferable in order to make it as formable as possible, and at the same time remain the soft squashyness of the foam. The foam required four layers of the silicone lacquer before the surface was saturated and without pores. This was tested simply by dipping the whole plug under water after curing each layer, while blocking the air entrance (pipe), and squeezing to look for bobbles, as shown in Figure 4.14.

The four-layer silicone lacquered foam was cut open to measure the final coating thickness, as this is considered an affecting factor on how the foam will react upon evacuating. The measured thickness was right under 0,2mm, and the cross section is shown in Figure 4.15.

[3] Dreve Lacquer B

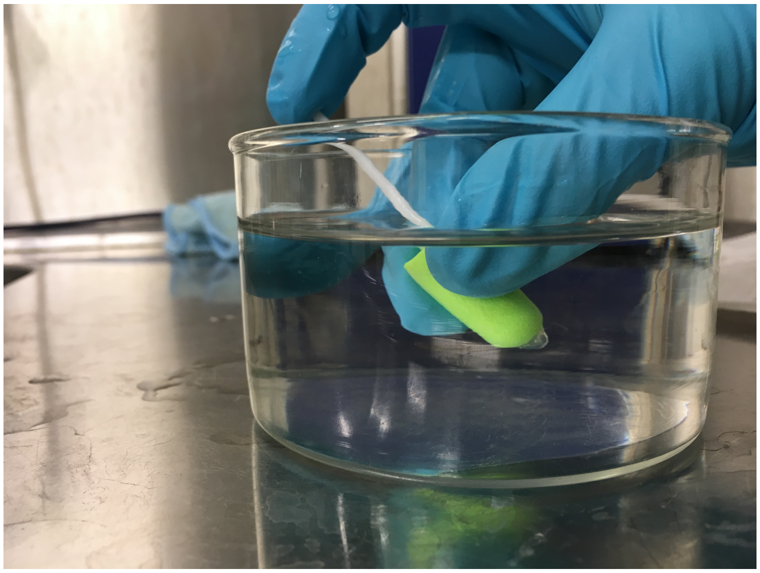


Figure 4.14: Air tight surface test.

Figure 4.15: The lacquered foam cut open.

4.2 Testing

4.2.1 Inserting the *Screw* Plug

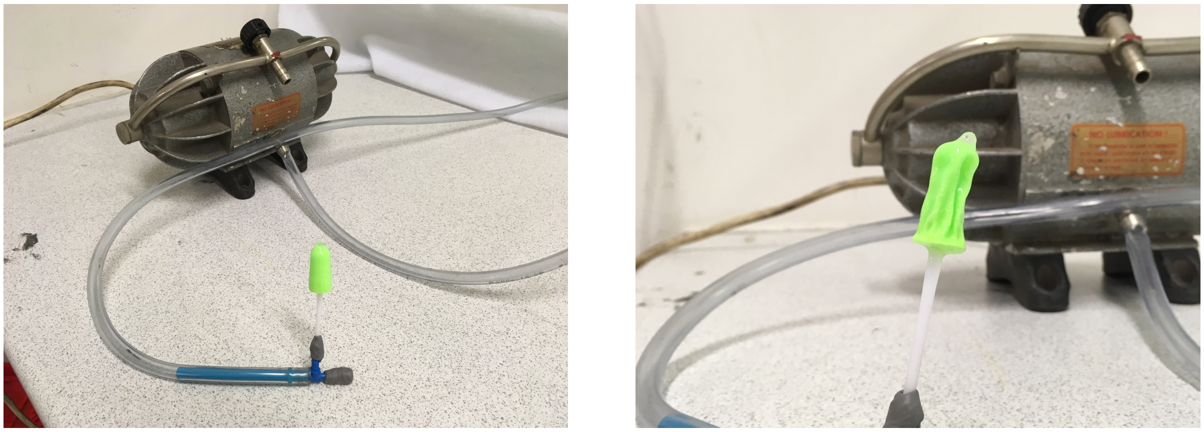
The *Screw* plug was tested by simply inserting it into the ear and see how well it went into the EAC, as shown in Figure 4.16. Measuring 17 mm from the bottom flange to the tip, there was never any risk of poking the eardrum during testing. The immediate observation was that the bottom part was too little to get a proper grip, in order to screw the plug in. This could easily be dealt with by designing it with a slightly bigger, non-circular knob. It turned out to be a little problematic to get completely in when just pushing. This resulted in the bottom flange not sealing against the posterior entrance of the ear canal. Since the helical flange does not completely block the sound itself, an improved version may also include some more blocking flanges along the core of the plug.

Figure 4.16: Testing insertion of the *Screw* plug.

4.2.2 Evacuation of the *Vacuum* Concept

To see if it was possible to evacuate the fourth concept, a setup with a electromagnetic piston pump[4] connected to the plastic pipe of the test piece was used, as illustrated in Figure 4.17a. Sticky tape was used for sealing openings and joints.

[4]Reciprotor 506R piston pump, 50W.



(a) Before evacuation. (b) After evacuation.

Figure 4.17: Test setup before (a) and after (b) evacuation.

Three different pieces of the *Vacuum* plug were tested, with several measurements done during testing. These observations will be presented in Section 4.3.

4.3 Results

This research on deep insert earplugs obviously ended up with a main focus on exploring the idea of evacuating a foam plug, which is described in detail in Subsection 4.1.5. Some key measurements from this test are tabulated in Table 4.2. Top and bottom diameter of the plug was the measured dimensions, illustrated in 4.18. Especially the top diameter (d_2) is a value of great interest as this is the part that has to go through the narrower parts of the EAC. This is likely to have been somewhat smaller if the silicone had cured without the dripping bulb at the top, or if this bulb was sanded down, regarding the structural reinforcement that it is causing. In addition, the time of evacuation and the time before fully expanded after releasing the vacuum were measured.

Test piece	d_1 [mm]	D_1 [mm]	d_2 [mm]	D_2 [mm]	Evacuation time [s]	Expansion time [s]
1	10,02	11,6	8-10	10,22	3,5	22
2	10,02	11,5	8,2-10	10,12	2,5	20
3	10,02	11,6	8,2-9,8	10,22	3	30

Table 4.2: Measured values from evacuation experiment with the *Vacuum* plug.

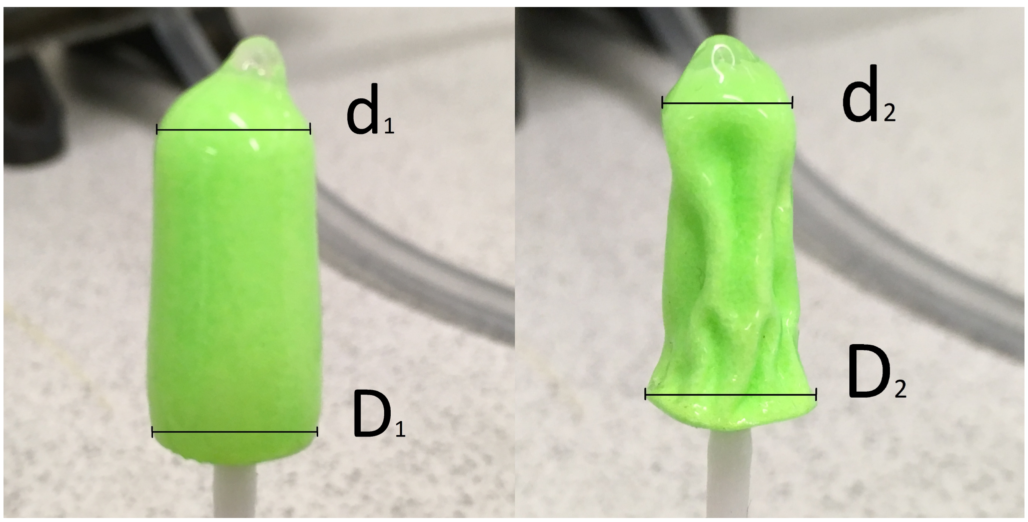


Figure 4.18: Dimensions before and after evacuation.

Chapter 5

Summary and Recommendations for Further Work

5.1 Discussion

The concepts that have been brought up all have their strengths and limitations. The *Screw* doesn't really satisfy the required properties of classifying as a deep insert. Its conical shape is great for guiding the plug unproblematically through the EAC, but the nature of its geometry makes it unable to seal against the bony part of the canal.

The *Vacuum* concept have shown some great advantages, but there are still some limiting aspects to it that have yet to be sorted out. It sure can hold its evacuated shape until ventilated, but the geometry is still too bulky and unpredictable. The folds that will form from evacuating the plugs, could possibly be dealt with by geometrical changes. In order to minimize the size of the folds this concept may require several sizes, which is inevitable in the case of a uni-ear solution. The results of the evacuation test, with the evacuated plug still being too big for the narrower parts of the EAC, are not considered too big of a problem. There were used standard size, full-length plugs that are not necessarily designed to go this deep. A shorter version foam plug with a smaller diameter would probably yield better results. The four layers of silicone lacquer are also considered a limiting factor of the last prototype, making it structurally more rigid. A different choice of foam might have contributed to a better solution.

Through working with the silicone lacquer, some new ways of manufacturing products were discovered. The lacquer has the advantage of being quickly curing and perfectly able to layer up. This brought up the idea of moulding geometries with internal cavities that requires cores with a negative draft angle. With the silicone lacquer it is theoretically possible get around this by filling the cavity of a two-piece mould, then pour it out so that it is just a thin layer of silicone sticking to the mould walls. By repeating this process, the walls can be just as thick as preferred. This is assumed to be one way of prototyping the Inflatable bladder, for instance.

5.2 Summary and Conclusions

Throughout the process of developing deep insert earplugs, it has been clear that meeting all the functional requirements of such a product is a challenging task. Even though the big breakthroughs may have yet to come in this project, several of concepts have been explored - some with the outcome of just eliminating inappropriate solutions, and some as proof of more promising solutions.

This exact project set out with a goal of meeting a set of objectives, in which understanding the challenges and getting down a certain groundwork was essential in order to handle the problem. Objective 1 has been met through a literature heavy, but important, part of the work. Getting to know the human ear properly, especially with respect to the external auxiliary canal, is fundamental for the approach to the developing process. A fair amount of journals and studies has been reviewed in Chapter 2, where relevant results and dimensional measurements are presented. Objective 2, which includes mapping out existing variants of earplugs, and detecting problems and benefits with them, is also met to a certain extent in Chapter 2. Variants of both hearing protecting plugs and hearing aiding plugs have been presented in a matrix. This has been a great way to get an overview of what has been tried out, what is working, and what properties to aim for in a new design. However, this process did not necessarily meet the part of detecting all the problems with the presented variants, due to lack of this kind of information. With these sections covered, Objective 3 was met by developing and exploring four concepts through morphological matrices and, to a varying degree, prototyping.

The concepts that have been brought up has certainly shown results with varying degrees of success, and with some of them still being rather unexplored. The first concept of an inflatable bladder didn't get too much attention due to lack of time, despite indicating some promising properties. The idea of using fluids, like in the concept of the *inflatable bladder*, as an attenuating and expanding medium, is interesting. As discussed in Section 4.1.2, it has some extraordinarily great benefits to it, and would definitely be something to explore if the time allowed for it. The second concept, of a mechanically squeezed foam plug, was shot down after yielding quite poor results from testing a rough prototype. The third concept, the earwax removing screw, was conceptually developed and designed in Solidworks. Functional prototypes were moulded, yielding a fine level of detail. The first iteration showed a few problems through testing, including a problem of getting the screw deep enough in the EAC for the bottom flange to seal properly. With the results from testing, in combination with not really classifying as a deep insert earplug, it was natural to leave the *Screw* concept without further iterations.

Concept 4, the *Vacuum* plug, is the one that yields most promising results in the sense of a deep insert earplug. The last iteration of prototypes, with a silicone lacquer coating, proves the concept of evacuating the plug and reventilating the air when properly inserted. The cross-section showed a decrease in diameter of up to 2 mm at the tip, after complete evacuation. Ranging from 8 to 10 mm, this still yields a diameter that is slightly too big for deep insertion. Looking at position S from 10 to 20 mm in Table 2.2, which will be an approximate span of a deeply inserted plug, the evacuated plug will be conflicted by the EAC. This concept still needs further work in order to serve as a deep insert earplug.

Some important steps on the way of developing a deep insert earplug has been done throughout this project. Lots of relevant theory and results from literature and studies have been enlightened and gathered. Some of the concepts also show promising results towards the solution to a deeply insertable and attenuating earplug.

5.3 Recommendations for Further Work

There are still some work to be done before reaching the goal of a uni-ear deep insert earplug. Based on the groundwork and development initiation in this project, there are several possible extensions that can be done. The remaining gaps would benefit from further research on the following points:

1. Prepare a list of metrics, as part of the product specification, so that properties of different prototypes are directly comparable. This would typically include specific dimensions that the plug has to fulfill, for instance based on the mean cross-sectional values with a certain standard deviation. The key here is defining the group of end users in which the plug will be applicable.

2. The concept of injecting fluids into a bladder, or simply having an elastic bulb containing fluids, is a field of concept that really should be put under scrutiny. The benefits of such a solution, described in Chapter 4, is too promising not to investigate further.

3. Being one of the concepts that were explored most deeply, the *Vacuum* plug truly shows some potential. If the geometry had been sized down and structurally changed, the idea might not be too bad. Being soft foam, the earplugs are obviously not easy to geometrically manipulate. One way of doing it, which apparently have been proven possible, is freezing the plug with liquid nitrogen, so that the material is easier to work with (e.g. by turning). The length of the plug also doesn't need to be that long, and about 5-10 mm would probably be sufficient. Another thing to improve is reducing the number of silicone layers, by trying different kinds of foam.

4. For the sake of the developing process, all aspects of production and prices have been neglected at this point, and are completely left out of the equation. At a longer-term basis, this is obviously something to take into account when approaching a final solution.

5. Another long-term recommendation is to look more closely into choice of materials. Not only is this crucial for the attenuation effect, but it also affects comfort and usability quite heavily. Taking the inflatable bladder as an example, how to avoid that the fluids gets uncomfortably cold or, in worst case, freezes during winter? Alcohol-based fluids will prevent it from freezing, and more oily fluids are assumed to cool down more slowly. These thoughts should be played around with in this case.

Appendix A

Acronyms

ASP Average sales price

EAC External auxiliary canal

HA Hearing aid

HP Hearing protection

HPD Hearing protection device

NPD New product development

PD Product development

PU Polyurethane

PVC Polyvinyl chloride

REAT Real-ear attenuation at threshold

SBD Set-Based design

SBPD Set-based product development

SD Standard deviation

SNR Single number rating

TM Tympanic membrane

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